Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A method of producing a sterile formulation comprising:

(a) mixing

(i) a cationic surfactant;

(ii) a polyoxyethylene (POE) and polyoxypropylene (POP) block copolymer; and

(iii) a polynucleotide;

at a temperature below the cloud point of said block copolymer to form a mixture; and

(b) cold filtering the mixture to produce a sterile formulation; wherein said method does not include ~~thermal cycling~~ raising the temperature of the mixture above and below the cloud point of said block copolymer.

2. - 5. (Canceled)

6. (Previously presented) The method of claim 1, further comprising aliquoting said formulation into a suitable container.

7. (Previously presented) The method of claim 1, wherein said block copolymer is of the general formula:

$HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

8. (Previously presented) The method of claim 7, wherein said block copolymer is the poloxamer CRL-1005.

9. (Previously presented) The method of claim 1, wherein said block copolymer is of the general formula: $HO(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$ wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

10. (Previously presented) The method of claim 1, wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride, benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc.

11. (Previously presented) The method of claim 1, wherein said mixing is performed at a temperature of about -2°C to about 8°C.

12.-17. (Canceled)

18. (Original) The method of claim 1, wherein said cold filtering is performed at a temperature of about -2°C to about 8°C.

19. (Previously presented) The method of claim 1, wherein said cold filtering is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

20. (Previously presented) The method of claim 1, wherein the final concentration of said cationic surfactant present in said formulation is from about 0.01mM to about 5mM.

21. (Previously presented) The method of claim 1, wherein the final concentration of said block copolymer present in said formulation is from about 1 mg/mL to about 50 mg/mL.

22. (Previously presented) The method of claim 1, wherein the final concentration of said polynucleotide present in said formulation is from about 1 ng/mL to about 10 mg/mL.

23. (Original) A cationic lipid selected from the group consisting of: Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc.

24. (Original) The cationic lipid of claim 23, wherein said lipid is Bn-DHxRIE.

25. (Original) The cationic lipid of claim 23, wherein said lipid is DHxRIE-OAc.

26. (Original) The cationic lipid of claim 23, wherein said lipid is DHxRIE-OBz.

27. (Original) The cationic lipid of claim 23, wherein said lipid is Pr-DOctRIE-OAc.

28. (New) A method of producing a sterile formulation comprising:

(a) mixing

(i) a cationic surfactant selected from the group consisting of Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc;

(ii) a polyoxyethylene (POE) and polyoxypropylene (POP) block copolymer; and

(iii) a polynucleotide;

at a temperature below the cloud point of said block copolymer to form a mixture; and

(b) cold filtering the mixture to produce a sterile formulation; wherein said method does not include raising the temperature of the mixture above and below the cloud point of said block copolymer.

29. (New) The method of claim 28, further comprising aliquoting said formulation into a suitable container.

30. (New) The method of claim 28, wherein said block copolymer is of the general formula:

$HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

31. (New) The method of claim 30, wherein said block copolymer is the poloxamer CRL-1005.

32. (New) The method of claim 28, wherein said block copolymer is of the general formula: $HO(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$ wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

33. (New) The method of claim 28, wherein said mixing is performed at a temperature of about -2°C to about 8°C.

34. (New) The method of claim 28, wherein said cold filtering is performed at a temperature of about -2°C to about 8°C.

35. (New) The method of claim 28, wherein said cold filtering is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

36. (New) The method of claim 28, wherein the final concentration of said cationic surfactant present in said formulation is from about 0.01mM to about 5mM.

37. (New) The method of claim 28, wherein the final concentration of said block copolymer present in said formulation is from about 1 mg/mL to about 50 mg/mL.

38. (New) The method of claim 28, wherein the final concentration of said polynucleotide present in said formulation is from about 1 ng/mL to about 10 mg/mL.

39. (New) The cationic lipid of claim 28, wherein said lipid is Bn-DHxRIE.

40. (New) The cationic lipid of claim 28, wherein said lipid is DHxRIE-OAc.

41. (New) The cationic lipid of claim 28, wherein said lipid is DHxRIE-OBz.

42. (New) The cationic lipid of claim 28, wherein said lipid is Pr-DOctRIE-OAc.